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*Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.*

*Therefore, this*

### United States Patent

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*J. Todd Pichini*

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*If the application for this patent was filed on or after December 12, 1980, maintenance fees are due three years and six months, seven years and six months, and eleven years and six months after the date of this grant, or within a grace period of six months thereafter upon payment of a surcharge as provided by law. The amount, number and timing of the maintenance fees required may be changed by law or regulation. Unless payment of the applicable maintenance fee is received in the Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period.*



US006004582A

**United States Patent** [19][11] **Patent Number:** **6,004,582****Faour et al.**[45] **Date of Patent:** **Dec. 21, 1999**[54] **MULTI-LAYERED OSMOTIC DEVICE**5,558,879 9/1996 Chen et al. .... 424/480  
5,681,584 10/1997 Savastano et al. .... 424/473[75] **Inventors:** **Joaquina Faour; Jorge Mayorga**, both  
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*Assistant Examiner*—Lakshmi Channavajjala  
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Strauss, Hauer & Feld, L.L.P.[73] **Assignee:** **Laboratorios Phoenix U.S.A., Inc.**,  
Buenos Aires, Argentina[57] **ABSTRACT**[21] **Appl. No.:** **09/086,871**[22] **Filed:** **May 29, 1998**[51] **Int. Cl.<sup>6</sup>** ..... **A61K 9/22; A61K 9/24**[52] **U.S. Cl.** ..... **424/473; 424/468; 424/472;**  
**424/474; 424/476; 424/475; 424/479; 424/482**[58] **Field of Search** ..... **424/468, 472,**  
**424/473, 476, 479, 482, 474, 475**[56] **References Cited****U.S. PATENT DOCUMENTS**

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The present invention provides a simple and improved multi-layered osmotic device (1) that is capable of delivering a first active agent in an outer lamina (2) to one environment of use and a second active agent in the core (5) to another environment of use. Particular embodiments of the invention provide osmotic devices in which the first and second active agents are similar or dissimilar. An erodible polymer coat (3) between an internal semipermeable membrane (4) and a second active agent-containing external coat (2) comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer. This particular erodible polymer results in an improved multi-layered osmotic device possessing advantages over related devices known in the art. The active agent in the core (5) is delivered through a pore (6) containing an erodible plug (7). The osmotic device (1) can be coated by a final finish coat (8).

**23 Claims, 1 Drawing Sheet**